

HOUSE BILL 3087
By Jones S

AN ACT to amend Tennessee Code Annotated, Title 53,
63, 68, and 71, to enact the "Cancer Drug
Donation Program Act".

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 68, Chapter 1, is amended by adding
the following as a new part 23:

SECTION §68-1-2301. This act shall be known as the "Cancer Drug Donation Program
Act."

SECTION §68-1-2302. For purposes of the Cancer Drug Donation Program Act the
following definitions apply:

(1) "Cancer drug" means a prescription drug used to treat cancer or its side
effects or used to treat the side effects of a prescription drug used to treat cancer or its
side effects;

(2) "Department" means the department of health;

(3) "Donor" means a person, health care facility, hospital pharmacy, drug
manufacturer, medical device manufacturer or supplier, wholesaler of drugs or supplies
or any other entity that donates cancer drugs, or supplies needed to administer such
drugs, in accordance with this act::

(4) "Health care facility" or "facility" means a facility as defined in §68-11-201(16);

(5) "Hospital" means a "hospital" as defined in §68-11-201(27);

(6) "Participant" means a physician's office, pharmacy, hospital, hospice, or
health clinic that has elected to participate in the program and that accepts donated

cancer drugs and supplies under the rules and regulations adopted and promulgated by the department for the program:

(7) "Pharmacy" means site of professional pharmacy practice regulated under Title 63, Chapter 10;

(8) "Physician's office" means the office of a person licensed to practice medicine and surgery or osteopathic medicine:

(9) "Prescribing practitioner" means a health care practitioner licensed under title 63 who is authorized to prescribe cancer drugs;

(10) "Prescription drug" means a drug as defined in Section 63-10-204;

(11) "Program" means the Cancer Drug Donation Program created by this act;

(12) "Supplies" means any supplies used in the administration of a cancer drug.

SECTION 68-1-2303. Any person or entity may donate cancer drugs to the program. Cancer drugs may be donated at a physician's office, pharmacy, hospital, hospice, or health clinic that elects to participate in the program and meets criteria established by the department for such participation. Cancer drugs will not be donated to a specific cancer patient. No such donated drugs or supplies may be resold by the program.

SECTION 68-1-2304. The cancer drugs or supplies donated to the program must be prescribed by a practitioner for use by an eligible individual and dispensed by a pharmacist.

SECTION 68-1-2305.

(a) A cancer drug or supplies shall only be accepted or dispensed under this program if such drug is in its original, unopened, sealed, and tamper-evident unit dose packaging, except that a cancer drug packaged in single unit doses may be accepted

and dispensed if the outside packaging is opened but the single-unit-dose packaging is unopened.

(b) A cancer drug shall not be accepted or dispensed under this program if such drug bears an expiration date that is no later than one year after the date the drug was donated, or if such drug is adulterated or misbranded as determined in subsection (c) below.

(c) Prior to dispensing to a patient, the cancer drugs or supplies donated under this program must be inspected by a pharmacist to determine that the drugs and supplies are not adulterated or misbranded.

(d) Any dispenser of donated products shall not submit a claim or otherwise seek reimbursement from any public and/or private third party payer for donated drugs dispensed to any patient in accordance with this program, and no public or private third party payers shall be required to provide reimbursement for donated drugs dispensed to any patient through this program.

SECTION 68-1-2306.

(a) A physician's office, pharmacy, hospital, hospice, or health clinic that accepts donated cancer drugs under the program shall comply with all applicable provisions of state and federal law relating to the storage, distribution, and dispensing of such donated cancer drugs.

(b) A physician's office, pharmacy, hospital, hospice, or health clinic who participates in the program may charge a nominal handling fee for distributing or dispensing cancer drugs under the program. Such fee shall be established in rules and regulations adopted and promulgated by the department.

SECTION 68-1-2307. Individuals who meet the eligibility standards for this cancer drug donation program shall not include patients who are eligible to receive drugs under the

state Medicaid program or under any other prescription drug program funded in whole or in part by the state.

SECTION 68-1-2308. The department, upon the recommendation of the board of pharmacy, shall adopt and promulgate rules and regulations to carry out the provisions of this part. Initial rules and regulations under the part shall be adopted and promulgated no later than ninety (90) days after the effective date of this part. Such rules and regulations shall include, but not be limited to:

(1) Eligibility criteria, including a method to determine priority of recipients under this program.

(2) Standards and procedures for participants that accept, store, distribute or dispense donated cancer drugs or supplies:

(3) Necessary forms for administration of the program, including, but not limited to, forms for use by persons or entities that donate, accept, distribute, or dispense cancer drugs or supplies under the program;

(4) The maximum handling fee that may be charged by a participant that accepts and distributes or dispenses donated cancer drugs or supplies;

(5) Categories of cancer drugs and supplies that the program will accept for dispensing;

(6) Categories of cancer drugs and supplies that the program will not accept for dispensing and the reason that such drugs and supplies will not be accepted: and

(7) Maintenance and distribution of the participant registry established in Section 68-1-2309.

SECTION 68-1-2309. The department shall establish and maintain a participant registry for the program. The participant registry shall include the participant's name, address, and telephone number and shall identify whether the participant is a physician's

office, a pharmacy, a hospital, a hospice, or a health clinic. The department shall make the participant registry available to any person or entity wishing to donate cancer drugs to the program.

SECTION 68-1-2311. Any donor of a cancer drug or supplies, or a participant in the program who exercises reasonable care in donating, accepting, distributing or dispensing cancer drugs or supplies under the Cancer Drug Donation Program Act and the rules and regulations adopted and promulgated under the act, shall be immune from civil or criminal liability and from professional disciplinary action of any kind for any injury, death, or loss to person or property relating to such activities.

SECTION 68-1-2314. No pharmaceutical manufacturer shall be liable for any claim or injury arising from the transfer of any prescription drug pursuant to the provisions of this act, including but not limited to liability for failure to transfer or communicate product or consumer information regarding the transferred drug, as well as the expiration date of the transferred drug.

SECTION 2. If any provision of this act or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to that end the provisions of this act are declared to be severable.

SECTION 3. The commissioner of health is authorized to promulgate rules and regulations to effectuate the purposes of this act. All such rules and regulations shall be promulgated in accordance with the provisions of Tennessee Code Annotated, Title 4, Chapter 5.

SECTION 4. This act shall take effect on July 1, 2006, the public welfare requiring it.